

REMARKS

Claims 1-80 were pending in the subject application. In this amendment, Applicants have amended claims 1, 3, 13, 29, 32, 33, 36, 39-41, 43 and 78; and canceled claims 5, 6, 14, 22-25, 44-60, 65-77, 79 and 80. Claims 1-4, 7-13, 15-21, 26-43, 61-64 and 78 are now pending in the subject application.

Claim 1 has been amended to specify that the protein-dalbavancin complex is part of a pharmaceutical composition; said endogenous protein-dalbavancin complex comprising a 1:1 complex of protein to dalbavancin, a 1:2 complex of protein to dalbavancin, or a mixture thereof; the pharmaceutical composition is sterile; and the endogenous protein is human serum albumin. Support for the amendment to claim 1 can be found in the original specification at, for example, page 3, ¶ [0011]; page 4, ¶ [0020]; pages 13-14, ¶ [0066]; and original claims 5, 6 and 13.

Claim 3 has been amended to correct a typographical error.

Claim 13 has been amended to specify that the pharmaceutical composition of claim 1 further comprises a pharmaceutically acceptable carrier. Support for the amendment to claim 13 can be found, for example, in original claim 13.

Claims 29, 32, 33, 36, 39-41 and 43 have been amended to remove their dependency from canceled claim 22.

Claims 78 has been amended to specify that the kit comprises the composition of claim 1. Support for the amendment to claim 78 can be found in the original specification at, for example, original claim 78.

No new matter is added by these amendments, and Applicants respectfully request their entry.

I. Rejection of Claims 44-60 and 69-76 under 35 U.S.C. § 101

The Examiner rejected claims 44-60 and 69-76 under 35 U.S.C. § 101 as allegedly not supported by either a credible asserted utility of a well established utility.

Applicants have canceled claims 44-60 and 69-76, thereby rendering the Examiner's rejection moot.

II. Rejection of Claims 44-60, 69-76 and 80 under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 44-60, 69-76 and 80 under 35 U.S.C. § 112, first paragraph for the reasons set forth in the office action. In particular, the Examiner states that "since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention."

Applicants have canceled claims 44-60, 69-76 and 80, thereby rendering the Examiner's rejection moot.

III. Rejection of Claims 1-80 under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1- 80 under 35 U.S.C. § 112, first paragraph as allegedly being non-enabling for the reasons set forth in the office action. In particular, the Examiner states that "the

specification, while being enabling for protein-dalbavancin complex wherein protein endogenous human serum albumin (HAS), [it] does not reasonable provide enablement for protein-dalbavancin complex wherein protein can be any protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in scope with these claims." The Examiner contends that "[s]ince there is no way to predict a priori which specific protein will result in a protein-dalbavancin complex having the desired property and activity, it would take an enormous amount of experimentation to determine the specific proteins useful in the claimed complex." Applicants traverse this rejection.

As a preliminary matter, Applicants note that claims 5, 6, 14, 22-25, 44-60, 65-77, 79 and 80 have been canceled, thereby rendering the Examiner's rejection of those claims moot.

Amended claim 1 of the application recites "a pharmaceutical composition comprising inter alia an endogenous protein-dalbavancin complex ... wherein said endogenous protein is human serum albumin." As conceded by the Examiner, the specification of the subject application is "enabling for protein-dalbavancin complex wherein protein endogenous human serum albumin (HAS)." Therefore, amended claim 1 and pending claims 2-4, 7-13, 15-21, 26-43, 61-64, 78 which depend directly or indirectly upon amended claim 1 are enabled.

In view of the above, Applicants request that the enablement rejection of pending claims 1-4, 7-13, 15-21, 26-43, 61-64 and 78 under 35 U.S.C. § 112, first paragraph be withdrawn.

IV. Anticipation Rejection of the Claims

The Examiner rejected claims 1-13, 22-25, 29-60, 77 and 79 under 35 U.S.C. § 102(b) as allegedly being anticipated by European Patent No. 0 199 882 ("the '882 European patent") for the reasons set forth in the office action. The Examiner also rejected claims 1-13, 69-71, 77 and 79 under 35 U.S.C. § 102(b) as allegedly being anticipated by Dowell et al., "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," 42 ICAAC, San Diego, CA, September 27-30 (2002) ("Dowell et al.") for the reasons set forth in the office action. Applicants traverse these rejections for the reasons set forth below.

1. The '882 European Patent

The Examiner states that "[t]he European Patent discloses the administration of dalbavancin for the purpose of treating bacterial infections (page 45). Since the formation of dalbavancin-protein complex inherently forms upon administration of dalbavancin as admitted by applicants on page 3 of the specification, the claimed complex and method are anticipated by the European Patent." Applicants traverse this rejection.

As a preliminary matter, Applicants note that claims 5, 6, 22-25, 44-60, 77 and 79 have been canceled, thereby rendering the Examiner's rejection of those claims moot.

Claim 1 has been amended to specify that the "endogenous protein-dalbavancin complex" is part of a pharmaceutical composition. Amended claim 1 further specifies that the composition is sterile and the endogenous protein is human serum albumin.

The '882 European patent describes antibiotic substances made from antibiotic A 40926 factors A, B, B₀, PA and PB; and the use of such substances in vitro and in vivo assays (see, e.g., 16,

line 15 to page 19, line 20). However, the '882 European patent does not disclose either expressly or inherently a sterile pharmaceutical composition comprising any endogenous protein-dalbavancin complex, let alone such a sterile a pharmaceutical composition where the endogenous protein is human serum albumin as recited in amended claim 1 of the subject application.

"[R]ejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in 'the prior art.'" *In re Arkley, Eardley, and Long*, 455 F.2d 586 (C.C.P.A. 1972). A prior art reference anticipates a claim if the reference discloses, either expressly or inherently, all the limitations of the claim. *EMI Group N. Am. v. Cypress Semiconductor*, 268 F.3d 1342, 1350 (Fed. Cir. 2001).

In summary, the '882 European patent does not disclose, either expressly or inherently, a sterile pharmaceutical composition comprising endogenous protein-dalbavancin complex where the endogenous protein is human serum albumin as recited in amended claim 1 of the subject application. Therefore, amended claim 1 and pending claims 2-4, 7-13 and 29-43, which depend directly or indirectly upon amended claim 1 are not anticipated by the '882 European patent.

In view of the above, Applicants respectfully submit that pending claims 1-4, 7-13 and 29-43 are not anticipated by the '882 European patent, and request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

2. Dowell et al.

The Examiner states that "Dowell et al disclose the administration of dalbavancin to subjects. Since the formation of dalbavancin-protein complex inherently forms upon administration of dalbavancin, the claimed complex is anticipated by Dowell et al." Applicants traverse this rejection.

As a preliminary matter, Applicants note that claims 5, 6, 69-71, 77 and 79 have been canceled, thereby rendering the Examiner's rejection of those claims moot.

Dowell does not disclose, either expressly or inherently a sterile pharmaceutical composition comprising an endogenous protein-dalbavancin complex where the endogenous protein is human serum albumin as recited in amended claim 1 of the subject application and as required by *In re Arkley, Eardley, and Long*, and *EMI Group N. Am. v. Cypress Semiconductor*. Therefore, amended claim 1 and pending claims 2-4 and 7-13 which depend directly or indirectly upon amended claim 1 are not anticipated by Dowell et al.

In view of the above, Applicants respectfully submit that pending claims 1-4 and 7-13 are not anticipated by Dowell et al., and request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

V. Rejection of the Claims 1-13, 22-25, 29-60, 69-77 and 79 under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-13, 22-25, 29-60, 77 and 79 under 35 U.S.C. § 103(a) as allegedly being obvious over the '882 European patent for the reasons set forth in the office action. In particular, the Examiner states that "[t]he European Patent discloses administration of dalbavancin for the treatment of bacterial infections (page 45) but does not disclose administration of dalbavancin in combination with additional antibacterial agents." The Examiner contends that "a person having ordinary skill in the art at the time the present invention was made would have been motivated to

combine two antibacterial compounds into a single composition, because such a person would have expected the resulting composition to possess broader spectrum antibacterial activity." Applicants traverse this rejection.

As preliminary matter, claims 5, 6, 22-25, 44-60, 69-77 and 79 have been canceled, thereby rendering the Examiner's rejection of those claims moot.

As noted above, the '882 European patent describes antibiotic substances made from antibiotic A 40926 factors A, B, B₀, PA and PB; and the use of such substances in vitro and in vivo assays (see, e.g., 16, line 15 to page 19, line 20). However, the '882 European patent does not teach or even suggest a sterile pharmaceutical composition comprising any endogenous protein-dalbavancin complex, let alone such a sterile a pharmaceutical composition comprising where the endogenous protein is human serum albumin as recited in amended claim 1 of the subject application.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981 (CCPA 1974)).

The '882 European patent does not teach or suggest a sterile pharmaceutical composition comprising any endogenous protein-dalbavancin complex, where the endogenous protein is human serum albumin as recited in amended claim 1 of the subject application. Therefore, amended claim 1 and pending claims 2-4, 7-13 and 29-43 are not obvious over the '882 European patent.

In view of the above, Applicants respectfully submit that pending claims 1-4, 7-13 and 29-43 are not obvious over the '882 European patent, and request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

VI. Nonstatutory Obviousness-type Double Patenting Rejection of Claim 22-25 and 29-43

The Examiner has rejected claims 22-25 and 29-43 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-22 of U.S. Patent No. 6,900,175 ("the '175 patent"). Applicants traverse this rejection.

As preliminary matter, claims 22-25 have been canceled, thereby rendering the Examiner's rejection of those claims moot.

Claim 1 has been amended to include the subject matter recited in original claims 6, 13 and 14, which the Examiner found nonobvious over claims 1-22 of the '175 patent. Claims 29-43 depend directly or indirectly on amended claim 1, so these claims are now also not obvious over claims 1-22 of the '175 patent.

In view of the above, Applicants request that the obviousness-type double patenting rejection of pending claims 29-43 be withdrawn.

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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